UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,785	04/25/2006	John Nolting	PA1394	2982

28390 7590 05/20/2009

MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
05/20/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No.	Applicant(s)	
	10/563,785	NOLTING, JOHN	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, 8, 12-14, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Sirhan et al. (US Patent No. 6,471,980).

Sirhan et al. teach a set of intravascular devices that deliver therapeutic agents that minimize or inhibit restenosis (see abstract). Sirhan et al. teach a stent with a plurality of coating layers that cover its length and where each contains a therapeutic agent (see Figure 7, column 8 line 24, column 11 lines 41-43; instant claims 1 and 12). The configuration shown indicates that the distal, proximal and middle regions of the stent have these therapeutic coatings (see instant claims 8 and 19). These coating layers are taught to include biodegradable/bioerodible polymers (see column 11 lines 1-4; instant claims 4 and 13). It is also taught that these devices are delivered by balloon dilation catheter (requiring that the stent and catheter be operably coupled) (see column 14 lines 11-13; instant claim 1). Claims 1 and 12 recite the intended use, “the therapeutic agents being released sequentially to inhibit restenosis adjacent to the ends of the stent.” A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to

patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the taught devices provide a layered drug configuration, it would be capable of sequential delivery of these therapeutics to inhibit restenosis. Further, Sirhan et al. teach a particular embodiment where different drugs are present in separate layers and envisioned to be released sequentially (see example 7). In addition these drugs include proteins and inhibitors of de novo nucleotide synthesis (anti-proliferative agents) (see instant claims 2 and 14). Thus claims 1-2, 4, 8, 12-14, and 19 are unpatentable over Sirhan et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 10-15, and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. (US PGPub No 2003/0033007 – see IDS - referred to henceforth as Sirhan et al reference B) in view of Sirhan et al.

Sirhan et al. reference B teaches that an edge effect phenomenon is known to occur in patients that have had coronary stents deployed within them (see paragraph 19). Beyond the edges of the implanted stent severe stenosis often develops, thus the inventors developed a device that focuses drug delivery from the proximal and distal ends of a stent device that extends beyond the ends of the stent (see paragraph 22). The intermediate portion (mid-portion) of the stent between the distal and proximal regions is taught to have a therapeutic agent that is different and released with a different kinetic profile than that released from the ends (see paragraph 51; instant claims 10). These therapeutic agents are taught to be present in coating form on the stent (see paragraph 59). Particular therapeutic agents envisioned on the device,

separately or in combination, include dexamethasone, rapamycin, rapamycin analogs, and prednisone (see paragraph 35; instant claims 3 and 15). Sirhan et al. reference B teaches that the stent is deployed via a balloon catheter (requiring that the stent and catheter be operably coupled) (see paragraph 48; instant claim 1). In addition, the presence of a biodegradable (bioerodible) rate controlling element (layer) that impedes the delivery of drug form the intermediate region (midportion0 as compared to the ends to different degrees is also taught (see paragraphs 25 and 33). Sirhan et al. reference B also teaches that the therapeutic has a higher diffusion rate from the device at the ends than in the intermediate region (mid-portion) (see claim 7; instant claims 11 and 22). Sirhan et al. reference B does not teach a multi-layered configuration of drug containing coatings.

Sirhan et al. teach a set of intravascular devices that deliver therapeutic agents that minimize or inhibit restenosis (see abstract). Sirhan et al. teach a stent with a plurality of biodegradable/bioerodible coating layers that each contains a therapeutic agent (see Figure 7, column 8 line 24, column 11 lines 41-43, column 11 lines 1-4; instant claims 1, 4, and 12-13). Since this layered configuration was known at the time of the invention to address the same pathology as that of Sirhan et al. reference B, it would have been obvious to one of ordinary skill in the art at the time of the invention to use this multi-layer configuration of drug containing layers to allow for the sequential delivery of a collection of therapeutic agents from the distal and proximal ends of the stent (see example 7; instant claims 1-2, 12, and 14). Therefore claims 1-4, 10-15, and 21-22 are obvious over Sirhan et al. reference B in view of Sirhan et al.

Claims 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US PGPub No. 2003/0153983).

Miller et al, teach medical devices with a set of layers on their surface that can each contain a different bioactive (see abstract and paragraph 55; instant claim 12). In particular, Miller et al. envision coronary stents as medical devices within their invention (see paragraph 92; instant claim 12). One of ordinary skill in the art at the time of the invention would have found it obvious to select a particular set of therapeutic agents pertinent to the body region treated by the device (e.g. coronary artery). Therapeutic agents considered by Miller et al. are taught to include paclitaxel, dexamethasone, and non-steroidal anti-inflammatory agents (see paragraphs 45 and 49; instant claims 14-15). These therapeutic containing layers are also taught to be composed of biodegradable (bioerodible) polymers (see paragraphs 40-41; instant claim 13). Miller et al. also teach that the layers are applied to any portion of the device, thus it also would have been obvious to apply them to the full length of the device (which includes the distal, proximal, and mid-portions) (see paragraph 50; instant claims 12 and 19-20). The layered configuration contains a plurality of barrier layers (timing coatings) and a plurality of therapeutic agent containing layers that alternate on the surface of the device (see paragraph 62; instant claim 16). These layers are taught to impede the release of therapeutic agents from the device (see paragraph 56; instant claim 18). Embodiments are envisioned where a barrier layer (timing coating) covers each of three therapeutic agent containing layers (see paragraph 62; instant claims 12 and 20). The

barrier layers (timing coatings) are also taught to be composed of biodegradable polymer (see paragraph 58; instant claim 7). In view of these teachings, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ bioerodible polymers in the barrier layers and/or the therapeutic containing layers. Therefore claims 12-20 are obvious over Miller et al.

Claims 1-3 and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. as applied to claims 12 and 14-20 above, and further in view of Sirhan et al. reference B.

Miller et al. make obvious a coronary stent with alternating barrier layers (timing coating) and therapeutic containing layers arranged such that the distal and proximal ends have a plurality of each while the mid-portion has at least one of each. In addition, the claimed therapeutic agents, release kinetics and bioerodability are also obvious over Miller et al (see instant claims 1-3 and 5-9). Miller et al. do not teach that the coronary stent is operably coupled to a catheter.

Sirhan et al. reference B teach that coronary stents are deployed via a balloon catheter (requiring that the stent and catheter be operably coupled) (see paragraph 48; instant claim 1). Therefore it would have been obvious to one of ordinary skill to operably combine a catheter and the taught coronary stent. Therefore claims 1-3 and 5-9 are obvious over Miller et al. in view of Sirhan et al. reference B.

Claims 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. reference B in view of Miller et al. as applied to claims 12 and 14-20.

Sirhan et al. reference B teaches that an edge effect phenomenon is known to occur in patients that have had coronary stents deployed within them (see paragraph 19). Beyond the edges of the implanted stent severe stenosis often develops, thus the inventors developed a device that focuses drug delivery from the proximal and distal ends of a stent device (see paragraph 22). The intermediate region (mid-portion) of the stent between the distal and proximal regions is taught to have a therapeutic agent that is different and released with a different kinetic profile than that released from the ends (see paragraph 51; instant claims 10). These therapeutic agents are taught to be present in a coating on the stent (see paragraph 59). Particular therapeutic agents envisioned on the device, separately or in combination, include dexamethasone, rapamycin, rapamycin analogs, and prednisone (see paragraph 35; instant claims 24-25). In addition, the presence of a biodegradable (bioerodible) rate controlling element (layer) in the intermediate region (mid-portion) and ends of the stent is also taught (see paragraphs 25 and 33). In addition, the stent is taught to be deployed via a balloon catheter (requiring that the stent and catheter be operably coupled) (see paragraph 48; instant claim 23). Sirhan et al. reference B does not teach a multi-layered configuration of drug containing coatings on the distal and proximal ends.

Miller et al. teach a coating configuration where different therapeutic agent containing coatings alternate with barrier layers (timing coatings) on the surface of a coronary stent. Since this particular configuration was known for its suitability in

delivering multiple drugs from a stent surface, it would have been obvious to employ it on the distal and proximal ends of the stent taught by Sirhan et al. reference B in order to confer its additional drug release beyond the ends of the stent upon implantation. This results in a stent with a tiered set of alternating barrier and therapeutic layers on the distal and proximal ends, while the intermediate region (mid-portion) contains a single pair of layers, one with therapeutic and the other a barrier layer.

The barrier layers taught by Miller et al. are actuated upon contact with physiological fluid. Once implanted, the outermost therapeutic agent would be released since it first encounters the physiological environment. Subsequently, the underlying barrier layer would contact physiological fluid and act as a diffusion barrier to the second therapeutic lying beneath it. After some time, depending upon the material chosen for these various layers, the second therapeutic would be released. As discussed above, Sirhan et al. reference B teaches that the intermediate region of the stent is coated with both a therapeutic distinct from those on the ends and a barrier layer. Like the barrier layers taught by Miller et al., it is actuated upon contact with physiological fluid which triggers the subsequent release of the therapeutic located beneath it. Therefore claims 23-29 are obvious over Sirhan et al. reference B in view of Miller et al.

Response to Arguments

Applicant's arguments filed February 5, 2009 have been fully considered but they are not persuasive regarding the rejections made under 35 USC 102(b) and 35 USC 103(a).

Regarding the rejection under 35 USC 102(b):

Applicant argues that Sirhan et al. does not teach sequential release of their active agents. The recitation of this attribute in the instant claims is not connected to any particular material that distinguishes them from the disclosure of Sirhan et al. In addition, this attribute is more an intended use than a structural limitation since no particular structure other than a coating has been linked to it, therefore as long as the structure in the prior art is capable of this use/function it meets the limitation. Moreover, in example 7, Sirhan et al. disclose stents with multiple coating layers, each containing a drug or drugs that are release sequentially. Regarding the placement of the taught coating on the device, the figures of Sirhan et al. depicting the various embodiments of the coated stents show the coatings spanning the length of the device, thereby being present on the proximal and distal ends.

Regarding the rejection under 35 USC 103(a):

Applicant argues that neither Sirhan et al. nor Sirhan et al. B teach sequential release of their active agents. As discussed above, Sirhan et al. does teach sequential delivery of the drugs contained in its coatings in example 7.

Applicant argues that Miller et al. does not teach sequential release of their active agents. Miller et al. does teach the use of a configuration of bioactive containing layers

alternating with barrier layers such that the compositions of each are modified to control their rate of release (see paragraph 62). These barrier layers are taught to be present in part to slow the release of drug contained in the inner most layers. Since it was contemplated to have the drugs deepest in the coating layers release slowest relative to those in the outer most layer, sequential delivery was certainly capable from these devices and follows from the teachings of Miller et al. Given a system where the rate of delivery of two different drugs contained in the same device is different and the slower releasing of the two is placed further from the device surface than the faster releasing drug, there is necessarily a period of time when the drugs are delivery sequentially (e.g. the period before the slow release drug has had enough time to reach the outermost surface). Thus the teachings of Miller et al. do make obvious to sequential delivery of drugs from its series of coatings on a stent device.

Applicant's amendments to the claims have overcome the rejections under 35 USC 112, therefore these rejections are hereby withdrawn. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The rejections and/or objections detailed above constitute the complete set presently being applied to the instant application.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward or Tracy Vivlemore can be reached on 571-272-8373 or 571-272-2914, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615